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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,091

01/16/2004

Thomas L. Cantor

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25225 7590 05/07/2009  
MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/760,091	<b>Applicant(s)</b> CANTOR ET AL.	
	<b>Examiner</b> JACOB CHEU	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-71, 78-84, 86, 92, 93 and 95-131 is/are pending in the application.
- 4a) Of the above claim(s) 47-68 and 98-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) -71, 78-84, 86, 92-93, 95-97, 108-131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/2/09; 4/24/09; 4/22/09; 8/29/08</u> .                       | 6) <input type="checkbox"/> Other: _____                          |



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## **DETAILED ACTION**

### **Status of Claims**

Applicant's amendment filed on 4/22/2009 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1-46, 72-77, 85, 87-91, 94 have been cancelled.

Claims 128-131 are added.

Claims 47-68 and 98-107 had been withdrawn. Claims 47-71, 78-84, 86, 92-93, 95-131 are pending.

Claims 69-71, 78-84, 86, 92-93, 95-97 and 108-131 are under examination.

### ***Petition on IDS expunge upon allowance, issue or abandonment***

The 33 documents (IDS filed on 4/23/2009) have been reviewed by Examiner. The decision would be made by Commissioner and Examiner would comply with the decision from Tech Center.

### ***Priority***

It is noted that Applicant argues the priority of instant case is based on its parent cases, i.e. US 09344039 (now US Patent 6743590) and US 09231422 (now US Patent 6689566). However, due to lack of support from the specification, the current application is accorded priority date based on its filing date, i.e. 1/16/2004 (See below New Matter Rejection)(Also see below).

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***Claim Rejections - 35 USC § 112***

***New Matter***

***PTH<sub>1-9</sub> and PTH<sub>1-10</sub>***

***Within a whole PTH with a higher affinity than its binding to a PTH fragment***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The rejections of claims 69, 71, 78-84, 86, 92-93, 95-97 and 108-131 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the instant claims 69, 78, 92 and 86 recite “an antibody binds to a bioactive epitope of a parathyroid hormone (PTH) in PTH<sub>1-8</sub> or PTH<sub>1-9</sub>, wherein said isolated antibody binds to said epitope within a whole PTH with a higher affinity than its binding to said epitope within a PTH fragment selected from a PTH<sub>1-8</sub> fragment, PTH<sub>1-9</sub>, PTH<sub>1-10</sub> and PTH<sub>1-34</sub> fragment”.

It is also noted that PTH<sub>1-9</sub> and PTH<sub>1-10</sub> are new matters not supported by specification.

The original specification amendment filed on 1/16/2004, at page 11, line 7, Applicant requested to enter SEQ ID No. 4 (human PTH 1-8 fragment) and SEQ ID No. 7 (rat PTH 1-8 fragment), where both the sequence has only 8 amino acid which spans from 1-8 of the PTH molecule (emphasis added).

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No 1-9 or 1-10 PTH fragment is disclosed. The disclosure is on 1-8 PTH fragment.

Additionally, although Applicant submitted Mr. Cantor's declaration (3/23/2007) indicating Figure 5 experiment was conducted by a PTH antibody purified by PTH 1-9 fragment (See page 2). However, it is not an obvious error falls into the category of remedial specification amendment under MPEP §2163- *"While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971)."* There is no discussion or statement regarding the 1-9, 1-10 or 1-34 PTH fragment throughout the specification with their affinity to the antibody compared to the whole PTH. Rather 1-8, 1-6, 1-13 PTH fragments are disclosed (See section 0035, 0038-39; original claims 62-63, 68, 72, 76-77). It is not an obvious error. Thus, it is still a new matter with regarding to PTH 1-9 and 1-10 fragments.

### ***Response to Applicant's Arguments***

It is noted that Applicant has amended claim language by deleting the term "three-dimensional". Thus, the rejection is moot on this issue. Furthermore, with respect to the feature "PTH fragment selected from a PTH<sub>1-8</sub> fragment to a PTH<sub>1-34</sub> fragment" (genus) has been amended selected species, including 1-8, 1-9, 1-10 and 1-34 fragment (emphasis added). Thus, the rejection on "genus" is moot based on the amendment. However, the recited feature still poses problem with written description (see below).

Applicant argues that support for the amended claims 69, 78, 86 and 92 for reciting "said isolated antibody binds to said epitope within a whole PTH with a higher affinity than its binding to said epitope within a PTH fragment selected from the group consisting of a

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PTH<sub>1-8</sub> fragment, PTH<sub>1-9</sub>, PTH<sub>1-10</sub> and PTH<sub>1-34</sub> fragment " can be found in an inherent binding property of an exemplary anti-PTH antibody used in the whole PTH assay as described in the present application. This inherent binding property has been described in Rebuttal Expert Report of Richard A. Lerner, M.D. (Lerner Report)(Exhibit B of the March 23, 2007 Amendment) at paragraph 5, pages 5-8 and Exhibits 2-7 of the Lerner Report. Applicant also points out the support from Figure 2 where the illustration of an antibody binds to PTH residues from 1-9. Finally, Applicant reiterates inherency properties of the instant application and argues that such characteristics provides adequate support for the feature of higher affinity to whole PTH compared to PTH<sub>1-8</sub> fragment, PTH<sub>1-9</sub>, PTH<sub>1-10</sub> and PTH<sub>1-34</sub> fragment (note, Applicant amended claim language deleting "to").

Applicant's arguments have been considered, but are not persuasive.

As discussed in the previous Office Action and the disclosure from the specification, there is only ONE PTH fragment versus whole PTH in binding affinity to the antibody was disclosed in the present specification (note, page 8, line 24-25 is merely the description of Figure 11). The experiment is conducted by a comparison of whole PTH versus 7-84 PTH fragment in Figure 11 (emphasis added; page 8, line 24-25 are Figure 11). Examiner also pointed out in the previous Office Action that fragment 7-84 PTH is even outside the recited range of PTH<sub>1-8</sub> fragment to a PTH<sub>1-34</sub> fragment (emphasis added). No disclosure of affinity of any other fragments, such as 1-8, 1-9, or 1-34 PTH fragment compared to the whole (1-84) PTH is disclosed. Neither Applicant's parent cases, No 09/344639 (now US 6743590) nor No. 09231422 (now US 6689566) discloses these features.

With respect to the inherency binding analysis, MPEP 2163.07 (a), "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is

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necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

Without further experimentation, i.e. Dr. Lerner’s study, one ordinary skill in the art would **NOT** have readily recognized that the instant antibody possesses such characteristics, namely “an antibody binds to a bioactive epitope of a parathyroid hormone (PTH) in PTH<sub>1-8</sub> or PTH<sub>1-9</sub>, wherein said isolated antibody binds to said epitope within a whole PTH with a higher affinity than its binding to said epitope within a PTH fragment selected from a PTH<sub>1-8</sub> fragment, PTH<sub>1-9</sub>, PTH<sub>1-10</sub> and PTH<sub>1-34</sub> fragment.

With respect to Figure 2, it is merely an illustration. The statement from the specification does not disclose 1-9 fragment or 1-10 fragment. Moreover, Figure 2 is a general concept of the instant invention by illustrating to one ordinary skill in the art how to use a capture antibody recognizing an N-terminal of PTH molecule. The figure itself does not convey any information with respect to the higher affinity of the antibody towards to whole PTH versus *any PTH fragment* (emphasis added). Additionally, Examiner notices that Applicant intended to "correct" Figure 5 in his Declaration by stating that the "1-8" fragment should have been "1-9" (See Declaration filed on 3/23/2007). If this is true, Applicant cannot recite BOTH the 1-8 and 1-9 PTH fragment in the claim language since Figure 5 only supports ONE PTH fragment (emphasis added). On its face, the literal and explicit support from the current specification, Examiner considers fragment 1-8 is the disclosure and found consistent throughout the specification. Furthermore, the binding affinity, albeit might be an inherent characteristic, does in fact needs to be further studied for verification, such as conducted by Dr. Lerner in the affidavits filed 2/23/07. Thus, such feature does not satisfy written description (Note, one has to read the claim in total, not only PTH 1-9 fragment, but also with its affinity characteristics). Otherwise, one ordinary skill when filing patent application, can always add new "inherent



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characteristics" to his/or her application. This practice is not recognized by this Office, and would not be fair to the public by unreasonably extending metes and bounds of patentee's invention.

Note, due to lack of support as discussed above, the priority for this case is therefore accorded its filing date 1/16/2004.

***Conclusion***

3. No claim is allowed.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/  
Examiner, Art Unit 1641